

### REMARKS

This amendment is being filed as a submission accompanying a Request for Continued Examination pursuant to 37 C.F.R. § 1.114 and before payment of the issue fee.

In the Office Action mailed on December 17, 2003, the Examiner rejected pending Claims 1-18 and 23-36 in this Application.

Claims 1-8, 13-18, and 23-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,407,609 to Tice et al.

Claims 8-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tice et al., in view of U.S. Patent 5,622,657 to Takada et al.

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tice et al., in view of Baker et al.

Applicants submit herewith amended Claims 1, 23, and 24. Claims 1, 23 and 24 have been amended to include “wherein no additional processing medium is required” to the step of “adding a biologically effective amount of a solid bioactive substance to the polymer solution” as well as “wherein the bioactivity of the bioactive substance is usefully preserved and wherein no additional emulsification or mechanical agitation is performed” to the step of “extracting the organic solvent from the emulsion.” Support for the amendments can be found throughout the Specification, examples of which are provided below.

The present invention solves the problems in the prior art just described by providing a *solid-encapsulation/single-emulsion/ solvent extraction technique* to encapsulate solid proteins and other bioactive substances into biodegradable microspheres. The present invention provides a cost-effective, scalable technique for producing microspheres loaded with biologically active proteins, and in particular solid proteins, together with compositions of such microspheres. [Pg. 7, ll. 1-11; emphasis added].

Microspheres of the present invention contain bioactive substances such as polypeptides, therapeutic agents or drugs. A particular feature of the present compositions is that *bioactive substances in their solid state, not dissolved in*

*solution, may be contained in the microspheres with the bioactivity of the substance preserved. Another feature of the present invention is that solid bioactive substances are incorporated into microspheres without using the atomization-freeze process familiar to those skilled in the art. Further, the present invention does not make use of a tissue homogenizer or an ultrasonic atomizer.* [Pg. 8, ll. 16-24 to pg. 8, ll. 3; emphasis added]

As such, Applicants submit that Claims 1, 23, and 24 are patentably distinguishable over the art cited. Namely, Tice et al. does not teach each and every limitation of Applicants' instant claims and each and every limitation thereof are not identical or anticipated by Tice et al. Applicants respectfully request the rejection to Claim 1 and those depending from Claim 1, namely Claims 2-8, 13-18, and 25-36, as well as Claims 23 and 24 be withdrawn under 35 U.S.C. § 102(e). Similarly, Applicants respectfully request rejections to Claims 8-11 under 35 U.S.C. § 103(a) and to Claim 12 under 35 U.S.C. § 103(a) be withdrawn. Applicants submit that Claims 1-18 and 23-36 are in condition for allowance.

New Claims 37-39 are presented in this amendment with language that excludes additional steps from being present in each claim. Support for new Claims 37-39 can be found in the examples presented above.

### CONCLUSION

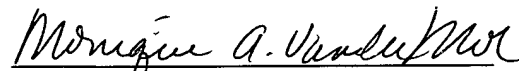
Consideration for allowance of the claims pending in this application pursuant to the filing of this Request for Continued Examination (RCE) is respectfully requested for the reasons set forth herein. As such Claims 1-18 and 23-36 as well as new Claims 37-39 are believed to be in condition for allowance.

The Examiner is requested to telephone the undersigned for any reason that would advance the application to issue.

This amendment and response increases the total number of independent claims from three (3) which were previously paid for to six (6), does not increase the total number of claims to more than previously paid for, and does not present any multiple dependent claims. Accordingly, we have enclosed our firm's check in the amount of \$514.00 to cover the cost of the filing of the RCE as well as the fee for the three (3) additional independent claims. It is now believed that no additional fees are required. However, should additional fees be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees other than an issue fee, from our Deposit Account No. 07-0153.

Dated this 17th day of March 2004.

Respectfully submitted,  
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